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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,903	12/21/2000	Hirokazu Ohbayashi	201001US0	6339

7590

12/18/2002

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EXAMINER

CHEU, CHANGHWA J

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 12/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/740,903

Applicant(s)

OHBAYASHI ET AL.

Examiner

Jacob Cheu

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Specification*

1. The abstract of the disclosure is objected to because legal phraseology such as “at least one of said two or more” is used. (See line 6) Correction is required. See MPEP § 608.01(b).

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 1 <sup>2,6</sup> and 2 are rejected under 35 U.S.C. 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1 (3), “to other substance(s)” is vague and indefinite. It is unclear what “other substance(s)” applicants refer to.

Similarly, claim 2 (3) shares the same problem with claim 1.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

5. Claims 1-26 are rejected under 35 U.S.C 102 (a) as anticipated by Ohbayashi et al. (USP 6252053).

Ohbayashi et al. teach an enzyme-carrier-antibody complex by conjugation method and multiple binding enzymes and antibodies to the moieties of the carriers. (See claim 1; Col. 3, line 10-18 and claim 10) Ohbayashi et al. teach conjugation carrier-enzyme or carrier-antibody by introducing either thio group or maleimide group to the carriers or enzymes. Although Ohbayashi et al. do not explicitly teach conjugating enzyme-antibody, nevertheless using reducing reagents to cleave the S-S bound in the antibody or fragments to generate thio group has the inherent binding capability to the carrier or enzyme modified by maleimide groups. Thus the limitations in the instant claim 1 (3) and claim 2 (3)(4) are met by Ohbayashi et al.

In addition, the antibodies have specificity for substance of interest. (See Col. 2, line 20-25) Ohbayashi et al. further teach selecting carriers of molecular weight ranging from 5,000-500,000 or 10,000-300,000. (See claims 5 and 10) In addition, Ohbayashi et al. teach using peptide polymers, i.e. polysine, containing amino groups or polysaccharide having aldehyde or amino groups as carriers. (See Col. 3, line 29-54) Ohbayashi et al. also teach using radish peroxidase, alkaline phosphatase, beta-galactosidase and glucose oxidase as enzymes source for immunoassay. (See claim 2) Furthermore, Ohbayashi et al. teach use antibody and fragment(s), i.e. F(ab')<sub>2</sub>, Fab' or Fabc' and streptavidin (See Col. 4, line 58-67 and Col. 7, line 50-54) As to claims 23-26 of instant invention, Ohbayashi et al anticipate the immunoassay kit because the reference discloses the complex as recited in claims 1 and 2. Further, Ohbayashi et al disclose immunohistochemistry and enzyme immunoassay. (See Col. 8, "Merit of the Invention") All the elements recited in the instant claim invention can be found out from the teachings of Ohbayashi et al. Therefore, claims 1-26 are anticipated by Ohbayashi et al.

### ***Conclusion***

6. No claim is allowed.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 8:30-5:00.

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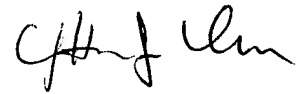
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu

Examiner

Art Unit 1641



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December 16, 2002



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
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12/16/02